

## PCT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner  
 US Department of Commerce  
 United States Patent and Trademark  
 Office, PCT  
 2011 South Clark Place Room  
 CP2/5C24  
 Arlington, VA 22202  
 ETATS-UNIS D'AMERIQUE  
 in its capacity as elected Office

Date of mailing (day/month/year) 08 February 2001 (08.02.01)	
International application No. PCT/SE00/01286	Applicant's or agent's file reference P0021PC
International filing date (day/month/year) 18 June 2000 (18.06.00)	Priority date (day/month/year) 21 June 1999 (21.06.99)
Applicant INGANÄS, Olle et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
 20 December 2000 (20.12.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was  
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No.: (41-22) 740.14.35	Authorized officer  Claudio Borton  Telephone No.: (41-22) 338.83.38
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## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 03 OCT 2001

PCT

Applicant's or agent's file reference P0021PC	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/SE00/01286	International filing date (day/month/year) 18.06.2000	Priority date (day/month/year) 21.06.1999
International Patent Classification (IPC) or national classification and IPC <sub>7</sub> A61B 17/00, A61B 18/00 // A61L 27/00, A61L 31/00		
Applicant MicroMuscle AB et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of \_\_\_\_\_ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 20.12.2000	Date of completion of this report 13.09.2001
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88	Authorized officer Anette Hall/EÖ Telephone No. 08-782 25 00

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE00/01286

## I. Basis of the report

### 1. With regard to the **elements** of the international application:\*

- ☒ the international application as originally filed
- ☐ the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, as amended (together with any statement) under article 19  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

### 2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language English which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☒ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

### 3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

### 4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheet/fig \_\_\_\_\_

### 5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2 (c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE00/01286

## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 5-10

because:

☒ the said international application, or the said claims Nos. 5-10

relate to the following subject matter which does not require an international preliminary examination (*specify*):

A method of treatment of the human or animal body by surgery  
(Article 34(4)(a)(i) and Rule 67(iv)).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 5-10

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE00/01286

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims	<u>1-4, 11-25</u>	YES
	Claims		NO
Inventive step (IS)	Claims	<u>1-4, 11-25</u>	YES
	Claims		NO
Industrial applicability (IA)	Claims	<u>1-4, 11-25</u>	YES
	Claims		NO

### 2. Citations and explanations (Rule 70.7)

The claimed invention relates to an array of micro-tools for surgery, e.g. clips, stents, tweezers. The tools consist of layered polymers being electrically operated to induce change of volume in at least one layer. The tools are mounted on a carrier having the form of a needle.

Document WO, 9837816, A1 discloses microfabricated therapeutic actuators made of a shape memory polymer (SMP), a polyurethane based material that undergoes a phase transformation at a specified temperature. By the use of such SMP material, SMP micro-tubing can be used as a release actuator for the delivery of embolic coils through catheters into aneurysms, for example.

Document US, 5771902, A discloses micromachined thin film cantilever actuators having means for individually controlling the deflection of the cantilevers, valve members, and rudders for steering same through blood vessels, or positioning same within a blood vessel. Such cantilever actuators include tactile sensor arrays mounted on a catheter or guide wire tip for navigation and tissues identification, shape-memory alloy film based catheter/guide wire steering mechanisms, and rudder-based steering devices that allow the selective actuation of rudders that use the flowing blood itself to help direct the catheter direction through the blood vessel.

None of the cited documents disclose micro-tools for surgery made of layered polymers being electrically operated to induce change of volume in at least one layer. The special technical features and the problems to be solved are completely different. Therefore, the invention described in claims 1-4 and 11-25 is not obvious to those skilled in the art.

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**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

International application No.

PCT/SE00/01286

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: V

Claims 1-4 and 11-25 consequently fulfil the requirements of novelty, inventive step and industrial applicability.

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
28 December 2000 (28.12.2000)

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(10) International Publication Number  
**WO 00/78222 A1**

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18/00 // A61L 27/00, 31/00

(21) International Application Number: PCT/SE00/01286

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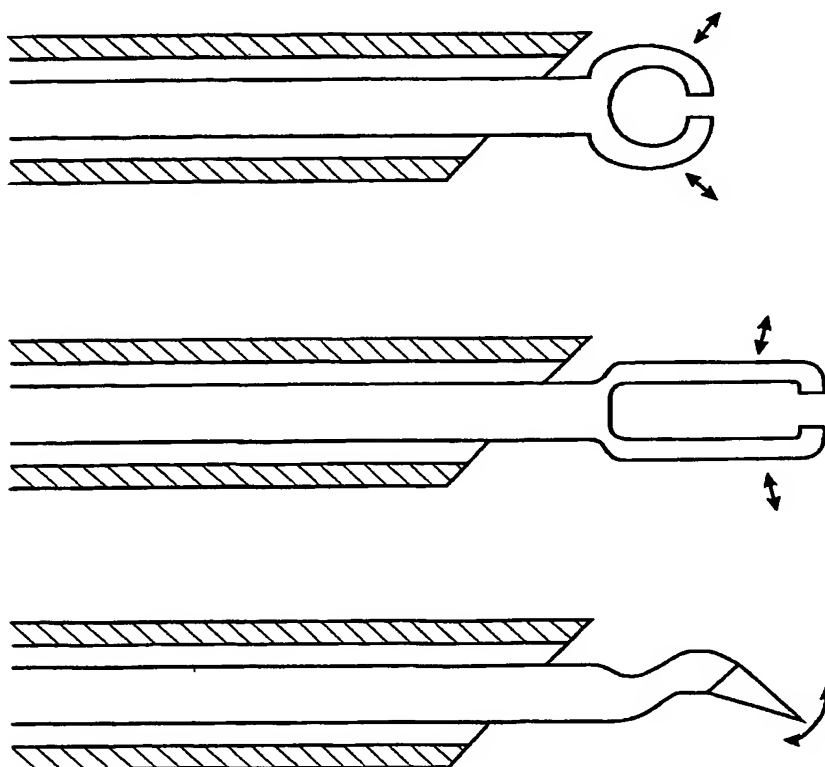
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(81) Designated States (*national*): AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

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[Continued on next page]

(54) Title: MICRO TOOLS



(57) Abstract: Tool arrays for biomedical surgery where the tools consist of layered polymer micromuscles arranged to induce geometrical changes and movements via an electrochemically induced change of volume in at least one polymer layer. The tool or tool arrays are mounted on a carrier having the form of a needle being inserted into a cannula/catheter through which the tools can be electrically actuated via external means to induce a mechanical movement to act upon biological structures.

WO 00/78222 A1



patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

**Published:**

— *With international search report.*



## Micro tools

This invention concerns micro-surgical tools that can be delivered through or by a catheter or needle. These tools or micro-structures can be used to adapt, assemble, separate, fortify, dilate, close and hold biological structures inside the body during and after surgery. The tools may be stents, valves, clips, nets, knives, scissors, dilators, clamps, tweezers etc.

## Introduction

The use of microstructures to assemble, fortify or dilate biological structures inside the body during and after surgery can help the surgeon in a number of ways. The operation of electrically actuated tools can help the surgeon to simultaneously position, operate manually, and observe. By positioning the tool by hand and separately operating it through external control (i.e. footswitch, voice control, other software-control) a much higher degree of precision is expected. In microsurgery, this is an especially desired advantage.

To be able to apply, beforehand or during an invasive procedure, a tool of a required size and geometry - designed for the purpose of cutting, drilling, holding, dilating, suturing, adapting or supporting - from tools that, for example, could be introduced through, placed inside or located at the end of a catheter or needle, is another desired function, requiring development of microactuators.

-The application of structures in or introduced through a catheter or needle is of particular interest at the application of tools, which are to be left at the site after insertion, and which have to execute their function for some limited time duration. The first example here is that of clips for surgery, sub-millimeter to millimeter structures, which would be used to hold two separated biological structures joined, for example during a healing period (Fig.1A - 1C).

-Another example is that of structures for controlling the flow through blood vessels. The simplest level is that of a clip used to prevent blood flow to a biological structure downstream in the blood flow. Such a clip, or series of clips, would be mounted and left to hold a firm grip

on the blood vessel and thus to prevent the flow of blood. In Figure 2 is shown a series of structures suitable for constricting blood vessels.

-The third example is at a somewhat more complex level with structures built in a geometry where they could be used inside or outside tube-like structures, as so called stents to dilate a stenotic area or to internally or externally fortify or join the structure(s) (Figure 5A and 5B). Stents are of particular interest since they are to be inserted inside the tube, then to be left there to expand a stenotic (examples: blood vessel, biliary duct) or to fortify a weak (examples: blood vessel with aneurysm, divided biliary duct) part of a tubular structure .

Arrays of fingers could be used to hold cylindrical objects, such as nerves and nerve fibers, or blood vessels. With the help of microactuators holding the structures (Fig. 3A - 3B), adjacent microstructures operating as neural sensing or activating electrodes, will enable recording signals from or activating nerves. This could be used as a synthetic neural connector, bridging a severed nerve or nerve fiber.

Elements with some temporary mechanical function could be inserted in membranes (Fig.4A - 4C). Insertion devices of this kind could be used for mounting a hole through a membrane such as commonly used in ear surgery for pressure equilibration. Making these as microdevices will much decrease the effort to place and remove the inserted devices and to keep them in place during the desired time period.

Clips, stents, finger arrays and insertion devices, once applied, could be resorbable or permanent. They could express various degrees of stimulation of cell growth on its surfaces, various degrees of anti-thrombotic activity as well as different antibiotic activities. They can also be carriers of various biochemical or biological components.

The necessary elements to accomplish these functions are the electrochemically activated micromuscles, built by micromachining thin metal and polymer layers (Elisabeth Smela, Olle Inganäs and Ingemar Lundström: "Controlled Folding of Micron-size Structures", Science 268 (1995) pp.1735-1738) or only polymer layers. These actuators can be produced in sizes from micrometers to centimeters, and operate well in biological fluids such as blood plasma, blood, buffer and urine. They are therefore suitable tools for micro invasive surgery inside the body.

The versatility of construction and the speed of response, as well as the force of these actuators render them as one of the best types of microactuators inside the body. An international patent covers one route of fabrication of such devices (A Elisabeth Smela, Olle Inganäs and Ingemar Lundström: "Methods for the fabrication of micromachined structures and micromachined structures manufactured using such methods ", Swedish patent application number SE 9500849-6, March 10, 1995 in succession also a PCT and international patent).

### Prior art

The combination of microactuators and catheters are not well documented in the literature. A patent search reveals a few examples but none that describes the use of microactuators as tools housed inside a catheter; several examples of microactuators use to position a catheter are to be found in the following patents

US5771902	Micromachined actuators/sensors for intratubular positioning/steering
US5819749	Microvalve
WO9837816A1	Microfabricated therapeutic actuators
WO9739688A2	Method and apparatus for delivery of an appliance in a vessel
WO9739674A1	Spring based multi-purpose medical instrument
US5855565	Cardiovascular mechanically expanding catheter

Several mechanisms are suggested for the microactuators in these applications, found among shape memory alloys (including polymeric materials) and piezoelectric materials. The use of conjugated polymers in micromuscles is not documented for catheter tools. Our novelty and innovation therefore resides in the use of microactuators based on conjugated polymers being electrically operated and mounted in or on a catheter or needle, to be positioned with the help of the catheter, and then activating the microactuator structures carried on the needle. The microfabrication of such microactuators renders possible a number of geometries from 10  $\mu\text{m}$  and larger, difficult to produce by mechanical production techniques. They may be produced by use of the method presented in patent A above and then mounted in or on the needle or catheter, or they might be produced by novel manufacturing methods. With the help of this invention, completely novel microsurgery tools are available.

The production of individually actuated tool arrays render little difficulty beyond that of producing the individual tool; we have to see that electrical contacts are supplied to actuate each microactuator separately. This can be done by wiring the single microactuator, to be used as the working electrode; the catheter is then used as the counterelectrode, and will be able to supply all the charge that we ever need to actuate all those microactuators. As wires may easily be produced in width down to 10  $\mu\text{m}$  with photolithography or with soft lithography, we will be able to put at least 50 microactuators along the tool array located in/on a needle of 1 mm width, with the simple philosophy of putting down parallel conductor wires. Should we need more, more elaborate addressing schemes might be needed.

Should a necessity for three electrode systems be found in any of the applications, microfabricated reference electrodes or macrosized reference electrodes carried on the catheter housing offers a solution for this problem.

Should the tool arrays be collectively addressed, and the tool array is designed to set free the outermost clip on actuation of all the clips, we will need a mechanism of confining the movements of all but the outermost clip. This is done by assembling the clip array into a cylindrical housing, preferably the catheter, prior to insertion in the body. The cylindrical housing is now confining the motion of microactuators, which search in vain to expand the strong metal casing on operation. When the outermost clip C1 is actuated, the clip is opened; likewise is the next-to-the outermost clip C2 partially free to move as it is protruding outside the cylindrical housing. Therefore the partial opening of C2 sets C1 free, as well as opens it up for subsequent spontaneous closing on the site to be clipped.

#### Figure captions

Figure 1A - 1C shows clips and clip arrays, where the clips are mounted in sequence, and area confined by a cylindrical housing, and where the activation of the outer most clip C1, opening up the clip to join the open structure W1, and then being set free by the simultaneous operation of C2, so as to be left at the structure W1, holding the structures together.

Figure 2 shows tubular tweezers, tweezers and knives, based on microactuators. The indicated movement is driven by microactuators properly mounted and designed.

Figure 3A - 3B shows a neural connector, where a number of small fingers coil around a cylindrical nerve to make a tight hold the nerve. Two separate nerves are here joined with the help of a common neural connector, which would be desired for accomplishing regrowth of the nerves. In addition, small electrodes can be fashioned along with the microfingers, and be used to sense or excite nerve signals.

Figure 4A - 4C. An insertion devise, for making a temporally permanent hole through a membrane. The devise is housed in a catheter/cannula/needle and is inserted through the membrane so as to make the devise form a hole through the membrane.

Figure 5A - 5B show a stent device.

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## CLAIMS

1. Tool arrays for biomedical surgery,  
characterized in that

5 (i) the tools consist of layered polymer micromuscles arranged to induce geometrical changes and movements via an electrochemically induced change of volume in at least one polymer layer, and

(ii) the tool or tool arrays are mounted on a carrier having the form of a needle being inserted  
10 into a cannula/catheter through which the tools can be electrically actuated via external means to induce a mechanical movement to act upon biological structures.

2. Tool arrays according to claim 1, characterized in that the layered polymer consists of a single layered polymer.

15 3. Tool arrays according to claim 1, characterized in that the layered polymer consists of a bi-layered polymer.

4. Tool arrays according to claim 1, characterized in that the layered polymer consists of  
20 multilayered polymer and metal layers.

5. Tool arrays according to one or more of claims 1-4, characterized in that the mechanical movement is used to position a biological structure.

25 6. Tool arrays according to one or more of claims 1-4, characterized in that the mechanical movement is used to hold a biological structure.

7. Tool arrays according to one or more of claims 1-4, characterized in that the mechanical movement is used to cut a biological structure.

30 8. Tool arrays according to one or more of claims 1-4, characterized in that the mechanical movement is used to dilate a biological structure.

9. Tool arrays according to one or more of claims 1-4, characterized in that the mechanical movement is used to fortify a biological structure.

5 10. Tool arrays according to one or more of claims 1-4, characterized in that the mechanical movement is used to implant a biological structure.

10 11. Tool arrays according to one or more of claims 1-10, characterized in that a number of identical tools are located on a tool array extending along a length of the cannula, catheter or needle, and wherein the actuation of a tool closest to the exit of the catheter is arranged to release a tool from the tool array and is arranged to leave it at the point of exit of the catheter in order to mount the tool at/in some biological structure .

15 12. Tool arrays according to claim 11, characterized in that a number of identical tools are located on the tool array extending along the catheter or needle and where each tool is arranged to become individually actuated.

20 13. Tool arrays according to claim 11, characterized in that a number of non-identical tools are located on the tool array extending along the catheter or needle and where each tool is arranged to become individually actuated.

25 14. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a clip arranged to join biological tissues or tissue parts, and arranged to hold the said tissues or tissue parts to allow healing.

30 15. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is an expandable cylindrical object designed to be inserted, in a contracted state, into a biological tube, and arranged to become expanded to keep said tube in an expanded state or to join two or more biological tubes.

16. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a scissors.

17. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a knife, which is arranged on an actuator, being arranged for linear and/or angular movement.

5 18. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a sharp needle that is arranged on an actuator being arranged for linear and/or angular movement.

10 19. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a dilator.

20. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a clamp.

15 21. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a tweezers.

22. Tool arrays according to one or more of claims 1-21, characterized in that the polymer micromuscles are built of layers, of which at least one is a conjugated polymer.

20 23. Tool arrays according to claim 22, characterized in that the conjugated polymer is selected from the group consisting of pyrrole, aniline, thiophene, para-phenylene, vinylene, and phenylene polymers and copolymers, including substituted forms of the different monomers.

25 24. Tool arrays according to claim 1, characterized in that the tool is built of bi-layered polymer, where the electrically activated volume change of said, at least one conjugated polymer is arranged to cause a bending of said bi-layer.

30 25. Tool arrays according to claim 1, characterized in that the tool is built of multilayered polymer, where the electrically activated volume change of said, at least one conjugated polymer is arranged to cause a bending of said multilayer.

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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 00/01286

## A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61B 17/00, A61B 18/00 // A61L 27/00, A61L 31/00  
According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61B, A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

\* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

15 Sept. 2000

Date of mailing of the international search report

11 -10- 2000

Name and mailing address of the ISA/  
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Anette Hall/Els  
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# INTERNATIONAL SEARCH REPORT

International application No.  
**PCT/SE 00/01286**

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: **5-10**  
because they relate to subject matter not required to be searched by this Authority, namely:  
**A method of treatment of the human or animal body by surgery or therapy (Rule 39.1(iv)).**
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).:

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.